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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,893	02/02/2000	Stephen J. Brown	014030.0147N1US /	6810

60683 7590 12/27/2006
HEALTH HERO NETWORK, INC.
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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/496,893

Applicant(s)

BROWN, STEPHEN J.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-98 is/are rejected.
- 7) ☒ Claim(s) 91 and 95 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03062006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 8/18/06, has been entered.

New claims 83-98, filed 8/18/06, are acknowledged.

The information disclosure statement filed 3/6/06 fails to fully comply with the provisions of 37 CFR 1.97, 1.98, and MPEP § 609, because references CA, CF, CF1, CP3, CT3, CB4 lack a publication date. Therefore, the information referred to in these references has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609, ¶ C(1). The remaining references in the information disclosure statement, filed 3/6/06, have been considered.

Claims herein under examination are 83-98.

Claim Objections

Claims 91 and 95 are objected to because of the following minor informalities: Claims 91 and 95 recite the phrase "the scripted queries and are adjustable" which does not make

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grammatical sense. Claim 91 also recites "using-" which is misspelled. Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 83-98 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method and system that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a method and system for identifying a disease-influencing gene which can be interpreted as transmitting and analyzing data, but does not result in a physical transformation of matter or produce/recite any concrete, tangible AND useful result. Therefore, these claims are not statutory. It is noted that one interpretation of the "sequencing the genotypes" and other steps in claim 83 is that they are drawn to computational steps that may take place entirely within the confines of a computer without any communication to the outside world or real world result. Ways to overcome this rejection include reciting a limitation whereby the physical matter is transformed (i.e. physical laboratory step) or

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outputting/displaying the result. It is noted that such a limitation must have written support in the originally filed application.

Claims Rejected Under 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 84-85 and 90-98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

Applicant points to written support on pages 13, 30, and 31 of the specification. There does not appear to be adequate written support for “are adjustable to each individual” (claim 84), “queries are adjustable” (claim 85), “scripted queries [...] are adjustable” (claims 91 and 95), “initial and updated” (claims 85, 91, 95), “whereby gene sequences from the genome analyses are compared with the responses to the scripted queries in the patient profile system to identify a disease-influencing gene in the individual” (claim 90), and “whereby gene sequences from the genome analyses are compared with the responses and measurements to the scripted queries in the patient profile system to identify a disease-influencing gene in each individual” (claim 94). There does not appear to be any written support for the “adjustable” and “initial and updated” limitations. While page 31 (lines 1-3) of the specification states “data mining techniques are

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used to compare the genotypes of the individuals between the categories”, this does not provide written support for “whereby gene sequences from the genome analyses are compared with the responses to the scripted queries in the patient profile system to identify a disease-influencing gene in the individual” (claim 90) and “whereby gene sequences from the genome analyses are compared with the responses and measurements to the scripted queries in the patient profile system to identify a disease-influencing gene in each individual” (claim 94) which differ in scope. Because the introduction of “are adjustable to each individual” (claim 84), “queries are adjustable” (claim 85), “scripted queries [...] are adjustable” (claims 91 and 95), “initial and updated” (claims 85, 91, 95), “whereby gene sequences from the genome analyses are compared with the responses to the scripted queries in the patient profile system to identify a disease-influencing gene in the individual” (claim 90), and “whereby gene sequences from the genome analyses are compared with the responses and measurements to the scripted queries in the patient profile system to identify a disease-influencing gene in each individual” (claim 94) do not appear to have written support in the specification, claims, and/or drawings, as originally filed, these phrases are considered to be NEW MATTER. Claims 92-93 and 96-98 are also rejected due to their dependency from claims 90 and 94.

Claim Rejections – 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 83-98 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

It is well known that the Human Genome Project has revealed that the number of human genes is in the range of 30,000. Even this number is controversial. Applicant's invention is directed to the clustering of individuals into groups based on responses to queries and then

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determining gene differences between groups in order to determine gene differences for identifying disease-influencing genes. It is also well known that a multitude of polymorphisms exists in human genes caused by environmental factors such as chemicals or cosmic rays. These complications result in an unpredictable length and difficulty in a research project that simply clusters individuals via queries regarding the behavior or other characteristics to then isolate or focus on one or more disease-influencing gene(s), even if guided by disease risk factors. It is known that some genetic sequences are correlated with particular diseased individuals, but that each of these sequences was elucidated by lengthy research projects where the findings of the gene sequence was difficult and unpredictable. Thus, the clustering of individuals, which has been known for many diseases already has not predictably resulted in gene identification, nor will the practice of the instant invention predictably result in the identification of disease-influencing gene(s). The publication of Doberstein et al. (previously mailed with a previous office action) was cited regarding paragraphs 0003-0008 to support the numerous difficulties involved in relating gene sequences to other factors even utilizing modern bioinformatics tools. It is also noted one skilled in the art would not scientifically conclude that simply comparing genotypes (instant claim 83) or comparing genes to query responses (instant claims 90 and 94) results in the identification of a disease-influencing gene. For these reasons, the instant claims are rejected due to a lack of enablement.

Applicant argues that the rejection is nullified due to claim amendments. This statement is found unpersuasive as the claim amendments still recite the non-enabled elements as described above.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 87 and 94-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 87 recites the limitation "the gene differences" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of any gene differences. Clarification of this issue via clearer claim wording is requested.

Claim 94 recites the limitation "the individual" in line 13. There is insufficient antecedent basis for this limitation in the claim as there is previous mention of "at least one individual" and "each individual" such that it is unclear which individual is being referred to in the phrase "the individual". Clarification of this issue via clearer claim wording is requested.

Claims 95-98 are also rejected due to their dependency from claim 94.

Conclusion

No claim is allowed.

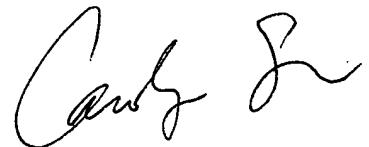
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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

December 14, 2006



Carolyn Smith
Examiner
AU 1631